Exhibit 596 [replacing Dkt. #2557-76] attached to Consolidated Reply Memorandum in Further Support of Plaintiffs' Motions for Partial Summary Adjudication with Respect to the Controlled Substances Act at Dkt. #2545.

- Redactions withdrawn by Defendant

DSJ1&2-PR Exh 596

RE: Report on House Energy & Commerce Subcommittee Hearing on DEA and FDA Transparency

From:

"Durbin, Adrian" <"/o=mckesson/ou=north america/cn=recipients/cn=e6xerws">

To:

"Berkey, Ann" <ann.berkey@mckesson.com>, "Shiraki, Matthew" <matthew.shiraki@mckesson.com>, "McDevitt, Mary" <mary.mcdevitt@mckesson.com>

Cc:

Nancy Macan McNally <nmm@vnf.com>, "Jordan A. Smith (jas@vnf.com)" <jas@vnf.com>

Date:

Wed, 09 Apr 2014 15:17:45 +0000

OK, thanks for the additional info. I'll make these changes and circulate just the one question.

Adrian Durbin
McKesson Corporate Public Affairs
415.983.8654 office
617.461.5653 mobile

From: Berkey, Ann
Sent: Tuesday, April 08, 2014 7:40 PM
To: Durbin, Adrian; Shiraki, Matthew; McDevitt, Mary
Cc: Nancy Macan McNally; 'Jordan A. Smith (jas@vnf.com)'
Subject: RE: Report on House Energy & Commerce Subcommittee Hearing on DEA and FDA Transparency

Quick work; thanks…

A couple of updates since my message yesterday on this. I met today with Gary Boggs, the new senior director of Reg Affairs for US Pharma for the east (of the MS River, that is!), who is based in Livonia. He is a former top official with the DEA and we talked extensively about this bill, the hearing, ways we can work with the agency, etc. He outlined in some detail the processes that DEA has had in place for years to "collaborate" with wholesalers and the way in which our industry (CAH especially) has blown them off…to the point that the DEA is now hammering all of us. Given that perspective, I would delete the first question. Burgess made the point at the hearing and it seems as if Holder has responded.

As to the second, I don't think we want to ask a question that we don't know the answer to…e.g. timeline for compliance with rescheduling. We are and will continue to push for an exemption; I would amend the question to ask only that part related to storage and handling for distributors. There is every reason for those provisions to apply to pharmacy.

Please copy Gary Boggs and me on the question you send to Don and Krista.

Thanks

Ann

Ann Richardson Berkey
Senior Vice President, Public Affairs
McKesson Corp.
One Post St.
San Francisco, CA 94104
415.983.8494 (office)
415.732.2694 (fax)
415.699.0632 (cell)
ann.berkey@mckesson.com

From: Durbin, Adrian
Sent: Tuesday, April 08, 2014 5:17 PM
To: Berkey, Ann; Shiraki, Matthew; McDevitt, Mary
Cc: Nancy Macan McNally; 'Jordan A. Smith (jas@vnf.com)'
Subject: RE: Report on House Energy & Commerce Subcommittee Hearing on DEA and FDA Transparency

Ann --

Below are a couple of draft questions that Matt and I put together today. Our strategy was to address topics helpful to us that were not addressed in the hearing. Let us know what you think, and if you want me to share them with Don, Krista, et al. Thanks.

1. In his testimony before the House Judiciary Committee on April 8, Attorney General Eric Holder stated that the DOJ recognizes that legitimate supply chain businesses are trying to do the right thing regarding prescription drug abuse, suggested that companies should have proper guidance, and offered to meet with companies to explore ways to work together. Will the DEA also commit to provide legitimate supply chain businesses with greater clarity and transparency, and offer to meet with these businesses to pursue collaborative ways to address prescription drug abuse?
2. Under the DEA's proposed rule to reschedule hydrocodone combination products (HCPs) from schedule III to schedule II (Docket No. DEA-389), pharmaceutical wholesale distributors would be required to build new vaults or expand existing vaults to store HCPs in compliance with schedule II requirements. There is no evidence that this provision would contribute to any additional patient safety benefit, but it would significantly increase operational costs and divert resources for wholesale distributors. Please provide the DEA's rationale for the need to impose these expensive and burdensome requirements on distributors (!) despite the lack of evidence that such measures would provide additional public benefit. How much time does the DEA plan to allow wholesale distributors to comply with the storage requirements of the proposed rule?

Adrian Durbin
McKesson Corporate Public Affairs
415.983.8654 office
617.461.5653 mobile

From: Berkey, Ann
Sent: Monday, April 07, 2014 9:21 PM
To: Durbin, Adrian; Shiraki, Matthew; McDevitt, Mary
Cc: Nancy Macan McNally; 'Jordan A. Smith (jas@vnf.com)'
Subject: FW: Report on House Energy & Commerce Subcommittee Hearing on DEA and FDA Transparency
Importance: High

Please draft some questions we can circulate to Don et al and then send on to Burgess and other members to file.

Thanks
Ann
Ann Richardson Berkey
Senior Vice President, Public Affairs
McKesson Corp.
One Post St.
San Francisco, CA 94104
415.983.8494 (office)
415.732.2694 (fax)
415.699.0632 (cell)
ann.berkey@mckesson.com

From: Berkey, Ann
Sent: Monday, April 07, 2014 9:18 PM
To: Walker, Donald; Walchirk, Mark; Starn, Frank
Cc: 'Nancy Macan McNally'; Durbin, Adrian; McDevitt, Mary; Shiraki, Matthew
Subject: FW: Report on House Energy & Commerce Subcommittee Hearing on DEA and FDA Transparency

Per our discussion with Rep. Burgess on Saturday, his office called me this afternoon before the hearing and asked me for questions that he could ask DEA. I shared the point Don had raised about their role as an enforcer and the frustrations this posed to working with the agency…as well as Mark's query about how to get the DEA to work more collaboratively with distributors. Note the recap below; he followed through…!
Burgess…and other members…now have 10 days to submit questions for the record. We will draft some from Public Affairs to share with you before we send to the Hill in case you have other thoughts.
Thanks…
Ann
Ann Richardson Berkey
Senior Vice President, Public Affairs
McKesson Corp.
One Post St.
San Francisco, CA 94104
415.983.8494 (office)
415.732.2694 (fax)
415.699.0632 (cell)
ann.berkey@mckesson.com

From: James Bayot [mailto:jpb@vnf.com]
Sent: Monday, April 07, 2014 3:56 PM
To: Berkey, Ann
Cc: Nancy Macan McNally; Jordan Smith
Subject: Report on House Energy & Commerce Subcommittee Hearing on DEA and FDA Transparency

Ann,
The House Energy & Commerce Subcommittee on Health held a hearing on "Improving Predictability and Transparency in DEA and FDA Regulation" which focused on three bills:

- H.R. 4069, the "Ensuring Patient Access and Effective Drug Enforcement Act"
- H.R. 4299, the "Improving Regulatory Transparency for New Medical Therapies Act"
- H.R. 4250, the "Sunscreen Innovation Act"

Here is a link to the witnesses' testimonies, and additional Subcommittee questions for the record are due by April 21.
The first panel featured ***Dr. Janet Woodcock, Director of FDA's Center for Drug Evaluation and Research***, who focused on FDA approval of sunscreen products.
The other witness, ***Joseph T. Rannazzisi, Deputy Assistant Administrator of DEA's Office of Diversion Control***, said the agency has not taken positions on the bills but he believes some of the witnesses at the hearing who support these DEA bills are trying to protect their clients from enforcement actions. During his testimony, Mr. Rannazzisi spoke about the drug scheduling process as well as efforts to reduce diversion and abuse. He spoke about DEA's administrative actions that may be taken against a registrant, including issuing a Letter of Admonition (LOA), holding an Informal Hearing (IH), or issuing an Order to Show Cause (OTSC) that could result in the suspension or revocation of a registration. ***Please note that McKesson was not mentioned during the hearing.***
Rep. Blackburn (R-TN) said that H.R. 4069, which she co-authored with Rep. Marino (R-PA), would provide important clarity about the definitions of "consistent with the public health and safety" and "imminent danger" in the Controlled Substances Act and would promote greater collaboration with industry and DEA. The DEA witness said the agency already works with prescribers, pharmacists, manufacturers and distributors on their responsibilities in the supply chain as it relates to flagging suspicious orders, prescriptions or patients.
Rep. Burgess (R-TX) talked about the DEA's lack of communication with, and intimidation of, drug manufacturers and distributors which negatively affects patient access to important medicines. He argued that DEA seems to care more about bringing enforcement action against pharmacies and distributors instead of working with them to fix problems.
Both ***Rep. Bilirakis (R-FL) and Rep. Griffith (R-VA)*** have heard complaints from pharmacists that distributors have cut off their pain medicine supply because of DEA quotas, but Mr. Rannazzisi disputed the idea of DEA limits on controlled substance orders and focused on the need for wholesalers and other supply chain participants to conduct due diligence and reporting on suspicious orders.
Rep. Ellmers (R-NC) questioned the witnesses about the appeals process for a suspended DEA registrant, and Mr. Rannazzisi said a registrant can appeal to a district court. The Congresswoman asked about how to limit overprescribing or illegal prescribing of controlled substances, and Mr. Rannazzisi emphasized DEA's limited resources to deal with the vast problem of Rx drug abuse and diversion.
When asked by ***Congressman Burgess*** about a potential Memorandum of Agreement between DOJ and HHS on drug information sharing, Mr. Rannazzisi said it is currently being negotiated but will generally allow for greater information sharing between the agencies. Dr. Woodcock said this new effort will be very beneficial for patient safety. ***Subcommittee Chairman Pitts (R-PA)*** asked the witnesses to submit additional information on the MOA.
On the second panel of witnesses, ***John Gray, President and CEO of HDMA***, spoke about the way that the ***Marino-Blackburn legislation (H.R. 4069)*** promotes greater clarity, consistency and collaboration between the federal government and stakeholders by establishing a corrective action plan for registrants and a Rx Drug Working Group. ***D. Linden Barber, a lawyer at Quarles & Brady and former Associate Chief Counsel at DEA***, testified about how H.R. 4069 defines "consistent with the public health and safety" and "imminent danger" in the Controlled Substances Act, and he believes these definitions will not impede DEA enforcement but will create greater legal foundation for DEA to curb bad actors.
When questioned by ***Chairman Pitts*** about the unintended consequences of DEA action, Mr. Gray said HDMA members lack guidance on interpreting suspicious orders and often will terminate relationships with pharmacies, which leads to a lack of supply for patients with legitimate needs.
Congresswoman Blackburn asked whether DEA should provide some type of report back to distributors to give them a bigger picture of troublesome ordering patterns. Mr. Gray said that HDMA members will go to DEA regional offices to talk about suspicious orders but the DEA staff say that cutting orders is a business decision. Mr. Barber also said that DEA often talks about the supply chain conducting due diligence on suspicious orders, but that term is not defined in the

regulations.

Rep. Green (D-TX) inquired about the role of distributors in preventing Rx drug abuse and diversion, and Mr. Gray answered that the industry provides Schedule II drug orders to DEA each week, but that information is not shared with distributors, who often make choices to cut off supply based on partial information. He said that the standard procedure has become to terminate supply when in doubt, and he noted HDMA has not heard back from DEA for guidance on when to reinstate sales to pharmacies thought to be suspicious.

James Bayot ¦ Director, Governmental Issues

VanNess

Feldman LLP
1050 Thomas Jefferson Street, NW
Washington, DC 20007
(202) 298-1838 ¦ jpb@vnf.com ¦ vnf.com